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510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for the Mammotome® *elite* Biopsy System 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990 the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

Company:

Devicor® Medical Products, Inc.
300 E-Business Way, Fifth Floor
Cincinnati, OH 45241
Establishment Registration Number: 3008492462

Contact:

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Date of Submission: August 18, 2011

Proprietary Name: Mammotome® *elite* Biopsy System

Common Name: Biopsy Instrument

Regulation: 21 CFR 876.1075

Regulatory Class: II

Product Codes: KNW

Predicate Device: Mammtome® EX Hand-Held System K033700; Bard Finesse™ Ultra Breast Biopsy System K093068.

Indication for Use of Device: The Mammotome® *elite* Biopsy System is indicated to obtain tissue samples from the breast or axillary lymph nodes for diagnostic analysis of breast abnormalities.

- The Mammotome® *elite* Biopsy System is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.
- The Mammotome® *elite* Biopsy System is intended to provide breast tissue for histologic examination with partial removal of a palpable abnormality.

The extent of a histologic abnormality cannot always be readily determined from palpation or imaged appearance. Therefore, the extent of removal of the palpated or imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality, e.g., malignancy. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

In instances when a patient presents with a palpable abnormality that has been classified as benign through clinical and/or radiological criteria (e.g., fibroadenoma, fibrocystic lesion), the Mammotome® *elite* Biopsy System may also be used to partially remove such palpable lesions. Whenever breast tissue is removed, histological evaluation of the tissue is the standard of care. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

Device Description: The Mammotome® *elite* Biopsy System is composed of a reusable Holster and a single-patient use, sterile Probe that may be used with ultrasound imaging guidance to excise and collect diagnostic samples with a single insertion of the Probe. The components of the system are designed to operate safely when used together for diagnostic sampling of tissue during a biopsy procedure. The Holster is a self-contained, handheld, reusable electro-mechanical vacuum-assisted biopsy device that consists of a rechargeable lithium-polymer battery and includes AC power cord and accessories. The Probe consists of an outer trocar shaft, a telescoping inner hollow coaxial cutter and an integrated coaxial cannula. The Probe incorporates a distal needle aperture and a proximal specimen collection cup with a tissue sample basket and specimen collection cap. The Holster contains one alignment tab that inserts into the holster notch located on the body of the Probe. The Probe body also contains two locking tabs to secure the Probe into the Holster. The Holster creates vacuum inside the device to assist in pulling tissue into the aperture while the sharpened inner cutter rotates at high speeds and extends across the aperture to acquire targeted tissue. The tissue sample is transported by vacuum to the specimen collection cup. The integrated coaxial cannula may be detached after the biopsy and remain in the breast to retain a track to the biopsy site when placing a biopsy site identifier.

Intended Use: The Mammotome® *elite* Biopsy System is intended to provide breast or axillary lymph node tissue samples for diagnostic analysis of imaged or palpated breast abnormalities.

Technological Characteristics:

The Mammotome® *elite* Biopsy System, used with or without imaging modalities, facilitates the diagnostic removal of tissue through a combination of vacuum and rotational/translational cutting functions. The Mammotome® *elite* Biopsy System utilizes the same primary components as identified in predicate devices to achieve its intended use: a Probe and housing/Holster and control module componentry.

The Probe needle and cutter are similar in both the Mammotome®*elite* Biopsy System and predicate devices. The need for the stand alone control module in the predicate device (Mammotome® EX Hand Held System) has been removed through the miniaturization of the components now self-contained in the Mammotome® *elite* Biopsy System Holster. These physical changes make the Probe/Holster more ergonomic and facilitate ease of use by physicians.

Software was created and integrated into the device (firmware) to eliminate the need for a stand-alone control module and provide the Mammotome®*elite* Biopsy System the capability for cutter advancement and specimen retrieval, transport and harvesting.

Supplied vacuum is used in the harvesting and transporting of acquired tissue samples, obviating the need for the mechanical specimen transport.

Performance testing:

To demonstrate substantial equivalence of the proposed device to the two identified predicate devices, side-by-side comparison of tissue sample collection, using both ex vivo and in vivo models, was performed. These models have historically been used to evaluate the ability for Mammotome® breast biopsy devices to collect tissue samples.

The Mammotome® *elite* Biopsy System and the two identified predicate devices were each used to obtain tissue samples. Each sample was evaluated against the following criteria:

- Tissue sample weight
- Tissue transport reliability
- Sample quality

Testing results confirmed that the Mammotome® *elite* Biopsy System would retrieve a tissue sample comparable to that of the identified predicate devices.

Conclusion: The claim of substantial equivalence of the Mammotome® *elite* Biopsy System to the predicate devices is based on the comparison of the intended use, product technical characteristics, and performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Devicor Medical Products, Inc.
% Ms. Shawna M. Rose
Director of Regulatory Affairs
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Cincinnati, Ohio 45241

MAR 20 2012

Re: K112411
Trade/Device Name: Mammotome® *elite* Biopsy System
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: KNW
Dated: March 9, 2012
Received: March 13, 2012

Dear Ms. Rose:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K112411

Device Name: Mammotome® *elite* Biopsy System

Indications for Use:

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In instances when a patient presents with a palpable abnormality that has been classified as benign through clinical and/or radiological criteria (e.g., fibroadenoma, fibrocystic lesion), the Mammotome® *elite* Biopsy System may also be used to partially remove such palpable lesions. Whenever breast tissue is removed, histological evaluation of the tissue is the standard of care. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112411